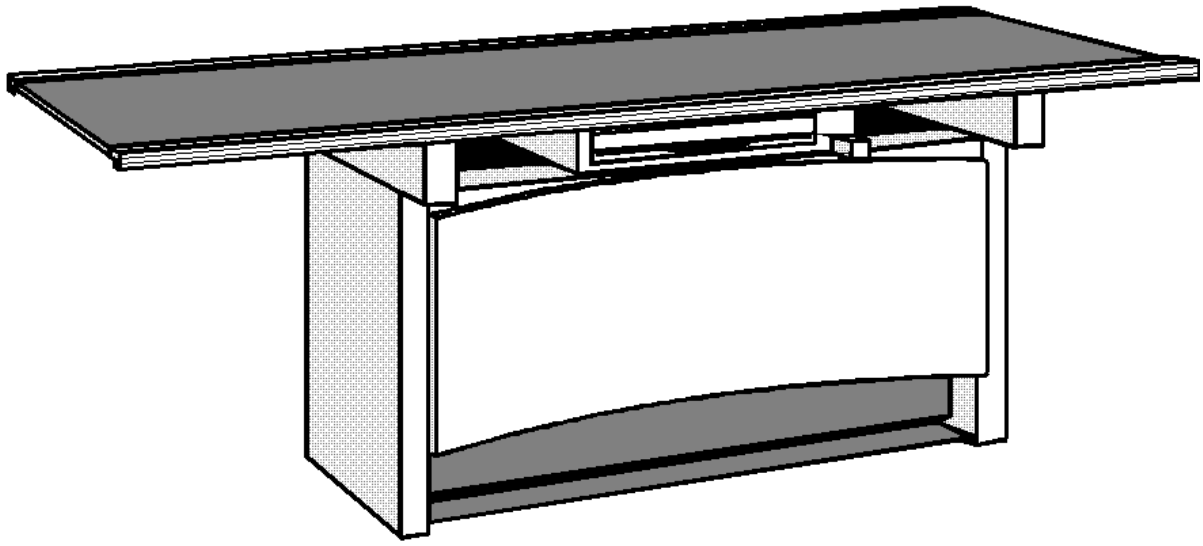
OPERATING INSTRUCTIONS COORDINATUS-2



CE 0125

English Edition

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Important Note:

To ensure proper operation of this product it is essential that the service personnel is familiar with the **"Operating Instructions"** which should be studied carefully before use.

Special attention is to be given to the chapter "Safety Notes"

The equipment must be used in accordance with the safety procedures described below, and must not be used for purposes other than those for which it was designed. The equipment may only be used by persons having recognised qualification, including adequate training in radiation protection, authorising them to perform the examination or treatment carried out.

It is the responsibility of the user to ensure that the government regulations are observed in the installation and operation of the equipment.

Technical safety note:

Regulations

If legal regulations govern the operation of the above equipment, it is the responsibility of the operator to observe them.

For the safety of patients, operators and others, as well the efficient functioning of the equipment it is necessary to have periodic service inspections at 12-month intervals according to the maintenance schedule. Please apply to your service organisation for inspection and maintenance.

Inspections intervals must by all means meet the requirements of the respective legislation or government regulations.

Changes and additions to the product must comply with the relevant legislation as well as with the accepted standards of good manufacturing practice.

As manufacturer of electromedical systems, we assume responsibility for the safety of the equipment only if maintenance, repairs and changes are carried out exclusively by us or third parties expressly authorised by us to do so, and if defective parts relating to the safety of the equipment are replaced by genuine spare parts.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of things or work ranges. Also the certificate should show the date of repair, the name of the service company and the signature of the technician.

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Before operating the equipment, the operator must check all devices concerning the safe and efficient functioning.

If the user of this equipment likes to combine the unit with other units, components or assemblies and this can not be made clear from the technical data, he must question us as manufacturer or another expert to make sure that the safety of the patients and operator is given by the planned combination.

Product Safety

Electrical safety

Only trained service personnel are permitted to remove covers and panels from the x-ray equipment .

In the Federal Republic of Germany, the electrical installation of rooms used for medical purposes must conform to the provisions of the VDE Standard 0107. In all other countries, the provisions of the applicable local laws and regulations have priority.
The unit is only prepared for solid installation with an all poled separation from the power (ICE 601, Kap. 57.1).

Mechanical safety

It is the responsibility of the operator to ensure safety of patient while the unit is in operation by visual check, proper patient positioning, and use of devices that are provided.

Danger of injury

The solid black arrows and dotted lines in the illustration show areas which present potential Danger of Injury to operating personal and patient from the equipment motion.

See next page.

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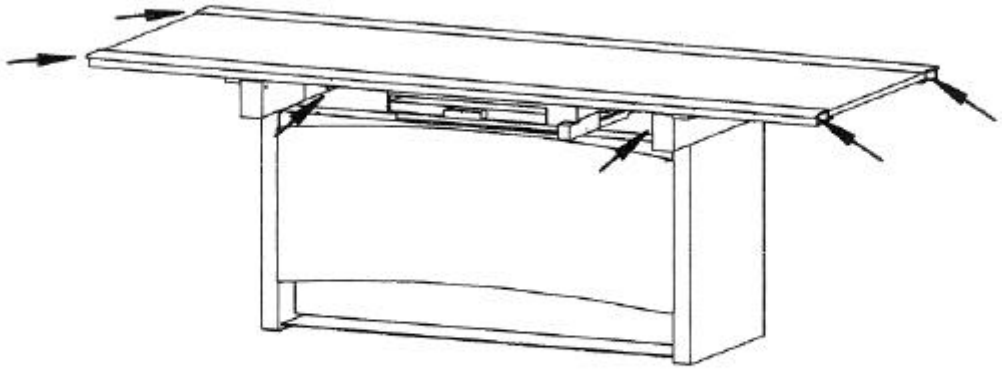

X-Ray Protection.

The unit has no controls with which radiation could be triggered.
Exposure is triggered only from the radiation-protected location of the generator.
The general radiation-protection measures must be observed.

In addition, we recommend the following:

1 Set the tube current as low as possible .
2 Limit the radiation field to the maximum possible extent.
3 Keep as fare away as possible.
4 Provide radiation protection for the patient.

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Explosion Protection

This equipment is not designed for use in areas where explosion hazard can take place.
Only skin cleansing agents may be used which form non-explosive mixtures with air.

Interference Suppression

The equipment complies with the EMC-requirements of the guideline 89/336 EWG. of

* Special board International Electronic Commission (IEC) This unit complies to EN 55011 and the reference value is according EN 55011 Group 1 Class B the international electrotechnical committee (IEC).

Classification of product

The equipment complies to the protection degree of Class 1 and for protection against electric shock Type B.

EC Conformity

The COORDINATUS-2 to which this declaration relates fulfils the essential requirements for safety of medical electrical equipment and follows the provisions of Medical Device Directive 93/42 EEC part 11 para. 5 according the procedure in annex VII.
The CE-Mark is only applicable for the product without X-ray components and Bucky.

The declaration of EC-conformity can be sent to you by request:
Write to:
Hans Pausch
Röntgengerätebau
c/o Quality Assurance Sys. Mgr.
Postfach 28 60
D-91016 Erlangen
Fax #: ..49 9131 99 24 22

Enviroment Condition

Surrounding temperature range	10° C to 40° C
Humidity	20% to 80%
Atmospheric pressure	700 hPa to 1100 hPa

Disposal of equipment
Legal waste disposal regulations may apply to the disposal of this product. To avoid causing damage to the environment and personal injury, we recommend that you contact your Customer Services representative before permanently removing this product from service.

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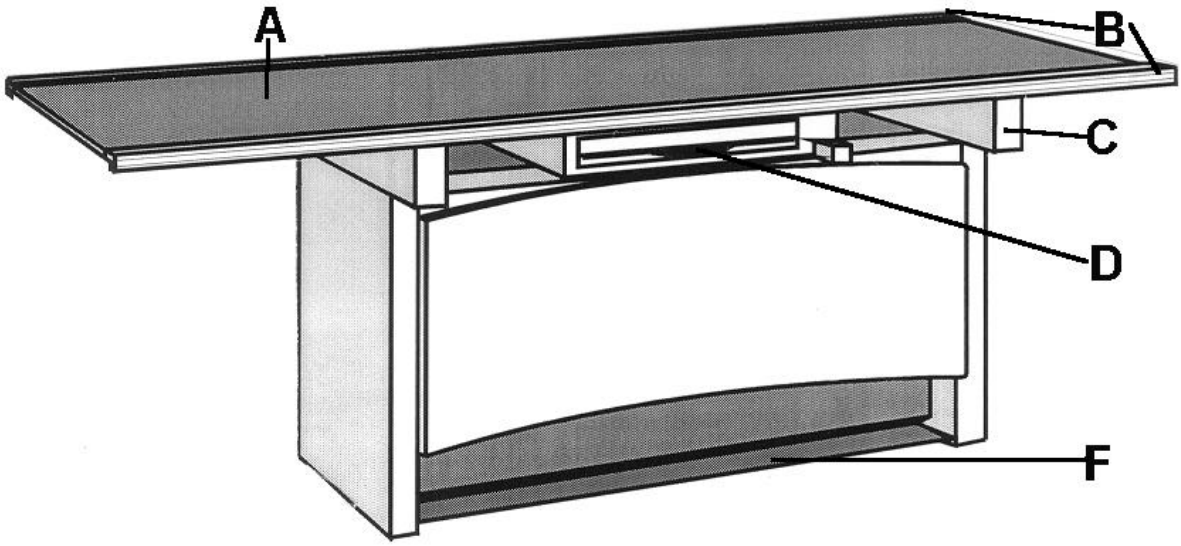
Design Features

Constructional Conception



A Table top, floating, manually movable, scratch-proof

B Profile rail with trim cover, smooth, accepts accessories

C Upper table frame

D Bucky unit, movable

F Table base, solid, vibration-free

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General

Short description

The equipment consists of a patient table with coordinate table top and diaphragm carriage.

The large and 2.20 m long, floating table top is manually movable and locks electromagnetically. The table top is provided for a maximum patient weight of 136 kg. It allows spacious lateral travel for fast and easy positioning of the patient (60 cms to the left, 50 cms to the right and 12 cms transversely).

Especially for patient comfort and easy cleaning, the table top offers a scratch-proof surface (Resopal) and trim-covered, smooth profile rails on both sides, which can accept accessories

The Bucky carriage accepts cassette trays from all renowned manufacturer. In longitudinal direction, it is manually moved and electromagnetically locked. The shortest possible FFD of 70 mm guarantees images of superior geometrical proportion. Low radiation absorption by the table top reduces the X-ray amount. The brake of the Bucky is released by a toggle switch on the operating handle.

The foot treadle along the table base allows the release of the electromagnetic table top brakes.

Range of use

The Coordinatus-2 is an universal X-ray examination table for doctor's practices as well as for hospitals. Large travel of the table top and uncomplicated functioning facilitate operation and increase patient comfort.

A special cassette holder is available for lateral exposures.

Prerequisition

For safe and efficient operation of this product the personnel must be familiar with the operating instructions. The chapter on „Safety procedures“ deserves special attention.

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Installation Requirements

Floor space

The unit is designed for stationary operation. The approximate floor space requires dimensions of 330 cm by 110 cm.

Height of room

The required room height depends on the type of tube stand used. Refer to the installation data of the manufacturer. The "Coordinatus-2" has a maximum working height of 85 cm above floor level.

Power

The system is equipped for single-phase alternating current with fixed installation. Two versions are available, depending on order. The unit is only prepared for solid installation with an all poled separation from the power (ICE 601, Kap. 57.1).
Without transformer, the system corresponds to nominal ratingsas follow:

Nominal voltage:	115/230 V AC
Nominal current:	2/1 A
Rated frequency:	50/60 Hz
Nominal capacity:	220 VA

Mains

The mains connection requires a 30 mA circuit breaker to be installed by the customer. The electrical installation must meet the relevant legislation, e.g. VDE 0107, IEC/SC 62A.

AL-equivalent

The weakening equivalent of the table top (patient pos. table top) is < 0,7 mm.

According to:

DIN EN 60601-1-3 mit 100 kV und HWS 3,7 mm AL

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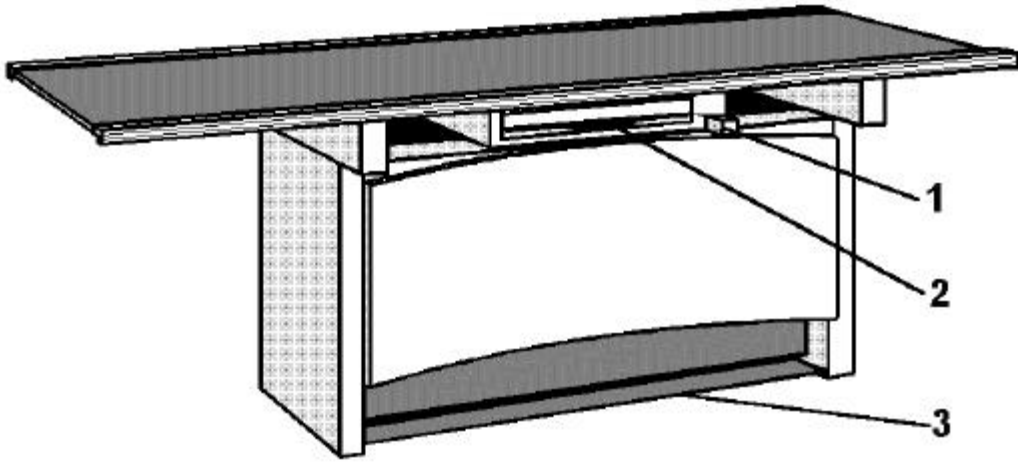
Arrangement



1 Toggle switch

2 Handle for cassette tray

3 Foot treadle

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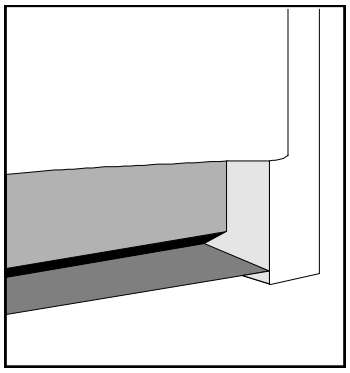
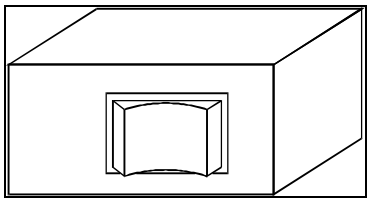
Meaning of Symbols/Function

Foot Treadle 13



unlocks the brakes for the floating table top. By fully pressing down and staying on the foot treadle, the table top can be moved manually in longitudinal and in transverse directions. Release of the foot treadle locks the table top in its changed working position.

Toggle switch

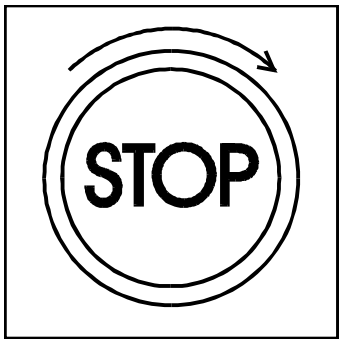


unlocks the brake for the Bucky. As long as the toggle switch is pushed, the carriage can be moved in longitudinal direction. Release of the push button locks the carriage in its changed position.

Operation

The equipment is ready for operation when switched on.

Emergency-off



If an emergency switch has been installed in the examination room, the red switch button must be pushed immediately in case of danger for patients, operating personnel or equipment. After positive elimination of the danger only, turn the red emergency-off switch clockwise to resume operation.

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Procedures before Exposure

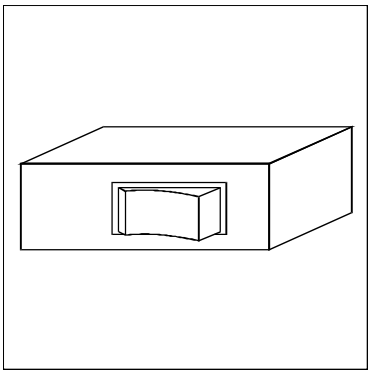
Positioning of Patient / Centering of Bucky, Exposure Object and Tube

Position the patient on the table top

Note
To prevent injury from the patient sitting down or being positioned, move the tube stand and tube out of the critical range before positioning the patient.

Centering of the object

Move the object into the central beam by adjusting the table top. For this purpose, press the foot treadle fully down. The brakes of the floating table top are now unlocked. Adjust the table top. Release the foot treadle. The table top is locked in position.



Centering of the Bucky

Push toggle switch and move Bucky to center into the exposure range.

Instructions for use regarding Buck's please see operating instructions from the manufacturer.
Information for operating the X-ray generator, the used tube stand and the limitation of the X-ray with collimator please see also operating instructions from the manufacturer.

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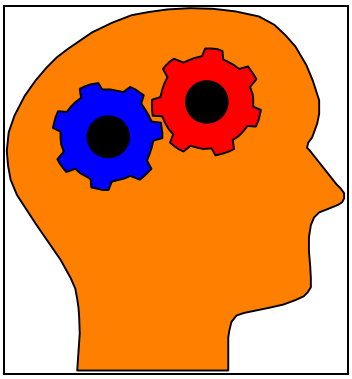
Centering of the radiation field

Use the cassette size sensing for optimal localisation of the radiation field of the collimator (operating instructions of the collimator).

Exposure preparation

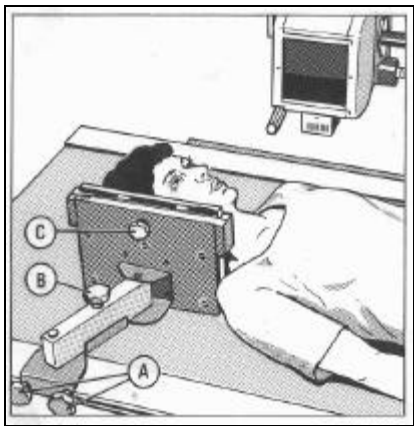
Insert cassette: Choose SID (FFD). Set exposure date on control desk. Control readiness for exposure. Command patient to „hold your breath“.

Note:
Do not forget radiation protection devices for the patient (lead rubber apron, gonad protection, etc.).



Lateral Exposure

For lateral exposures with the cassette holder lateral (see also chapter with accessories) rotate the tube stand to a 90° angle. Then rotate the tube to a 90° angle (indication of angle!).



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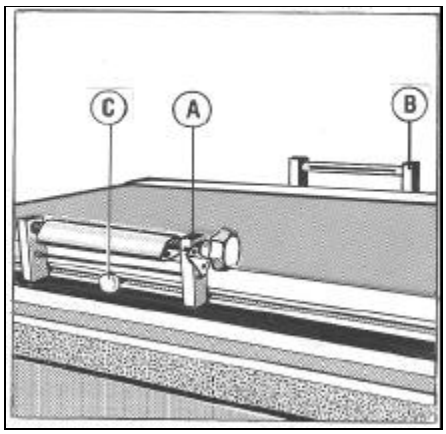
Accessories

Compression Belt / Head Supports / Hip Clamps / Table Mattress

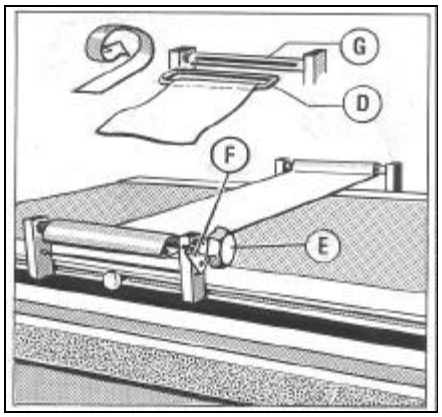


Compression Belt

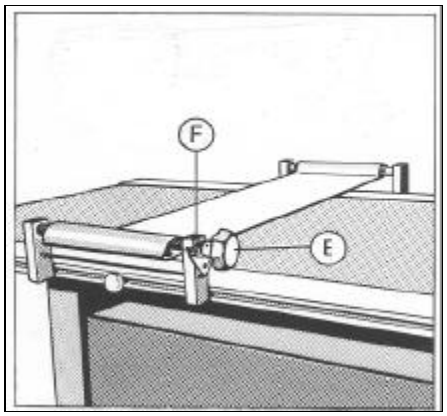
Fastening and application:

Slide support frame **B** into profile rail at wall side or into Bucky profile rail. Turn knob screw to clamp in position.

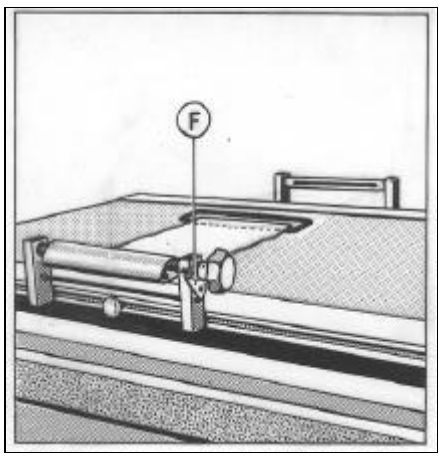
Slide tightener **A** into front profile rail (operator side). Turn hand screw **C** to clamp in working position opposite of **B**



Press ratchet mechanism **F**. Unroll belt and stretch across patient.



Guide belt through complementary frame and once around frame bar. Fix belt bracket **D** into slot of shaft **G**. Turn ratchet mechanism **E** to tighten belt.



Untightening:

Press locking lever **F**

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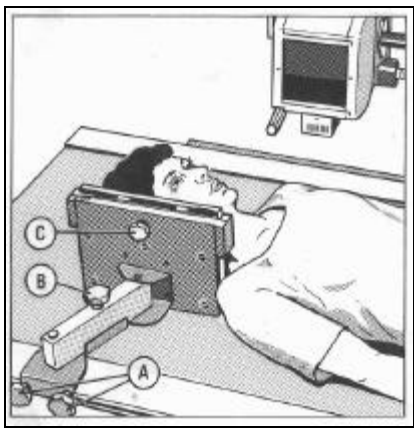
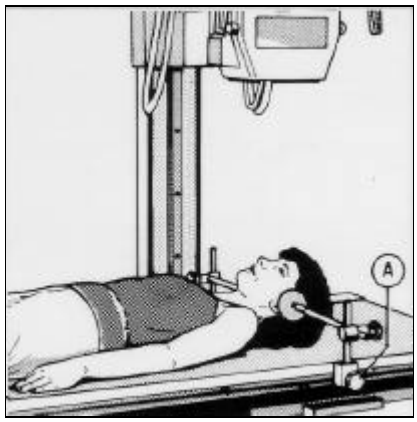
Lateral cassette holder



The lateral cassette holder permits lateral exposures if the tube unit is mounted to a tube swivelling device.
The lateral cassette holder is slipped in one of the profile rails.

Grip screw **A**: secures the holder at the table top
Grip screw **B**: locks the holder setting
Grip screw **C**: fixes the lateral position of the cassette clamps.

Head Supports

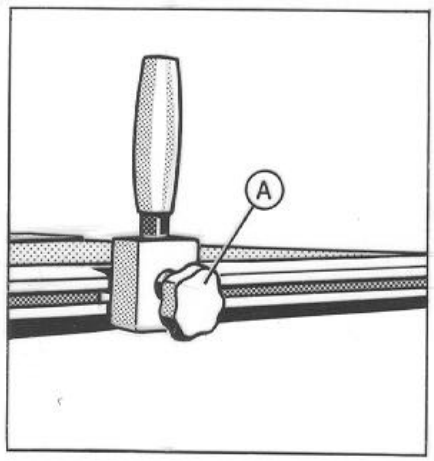


The head supports slide into profile rails of the table or Bucky. The supports can be clamped in any position desired. The patient`s head is fixed to the appropriate exposure position by cushioned plates on adjustable bars.

Handscrew **A**: Clamping Head Supports to table top or Bucky.

Hand screw **B**: Clamping of head holder

Hand grips



The hand grips are slipped in the profile rails of the table. They may be fixed at any position and offer a reliable hold for the patient.

Grip screw (**A**): secures the grip in place

Important note:

The positioned patient may only hold on to the hand grips. In no case may he put his hands around the edge of the table top.

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Maintenance:

Important note:
Like all technical equipment, this unit requires also a regular maintenance service to increase the safety of the equipment.

Operator's service and maintenance

The operator has to check the x-ray equipment for defects as listed below:
In case of functional defects or other deviations from the normal operation the equipment has to be switched off at once and the service company has to be informed.
The equipment can not be used before all defects have been eliminated.

Daily routine checks

Check indicator light and operating elements for proper functioning.

Weekly checks

Check all cables and their connections for treaces of wear.

Periodic maintenance

For trouble-free operation of the COORDINATUS-2 as well as safety for patient and user it is necessary to carry out a technical maintenance from the service company every 12 months.

Please see „technical maintenance" of the mounting instruction.
The steel rope of the column has to be replaced every three years.

Attention:
In case of failure from components, which can limit the safety of the equipment, original spare parts have to be used.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of work that was done. Also the certificate should show the date of repair, the name of the service company and the signature of the technician.

Cleaning:

The equipment must be switched off before cleaning. Plastic surface should only be cleaned with mild soap. Do not use strong cleaners or solvents as they will damage the finish or blur the lettering.

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At least once a month external parts and exposed tracks on which rollers move should be wiped to remove foreign material that may have accumulated.
DO NOT USE A DAMP CLOTH.
Wipe the tracks with a cloth lightly soaked with light machine oil or WD-40.

To protect the finish, polish the equipment with PURE liquid paste wax. Do not use wax containing a cleaning substance. Polish all enamelled metal surfaces.

Disinfection:

The equipment has to be switched off before disinfection. Only disinfection methods can be used that correspond to the relevant regulations and rules as well as the protection for explosion.
Spray disinfection is not recommended because it can get in the inside of the x-ray equipment.

The Council Directive 93/42/EEC on Medical Devices Article 12

This document is revised at the moment by the council.

However the Article 12 must be followed by the company or the legal person who put this X-ray unit into worke.

The user is responsible for compliance and implementation of national deviations in the EC.

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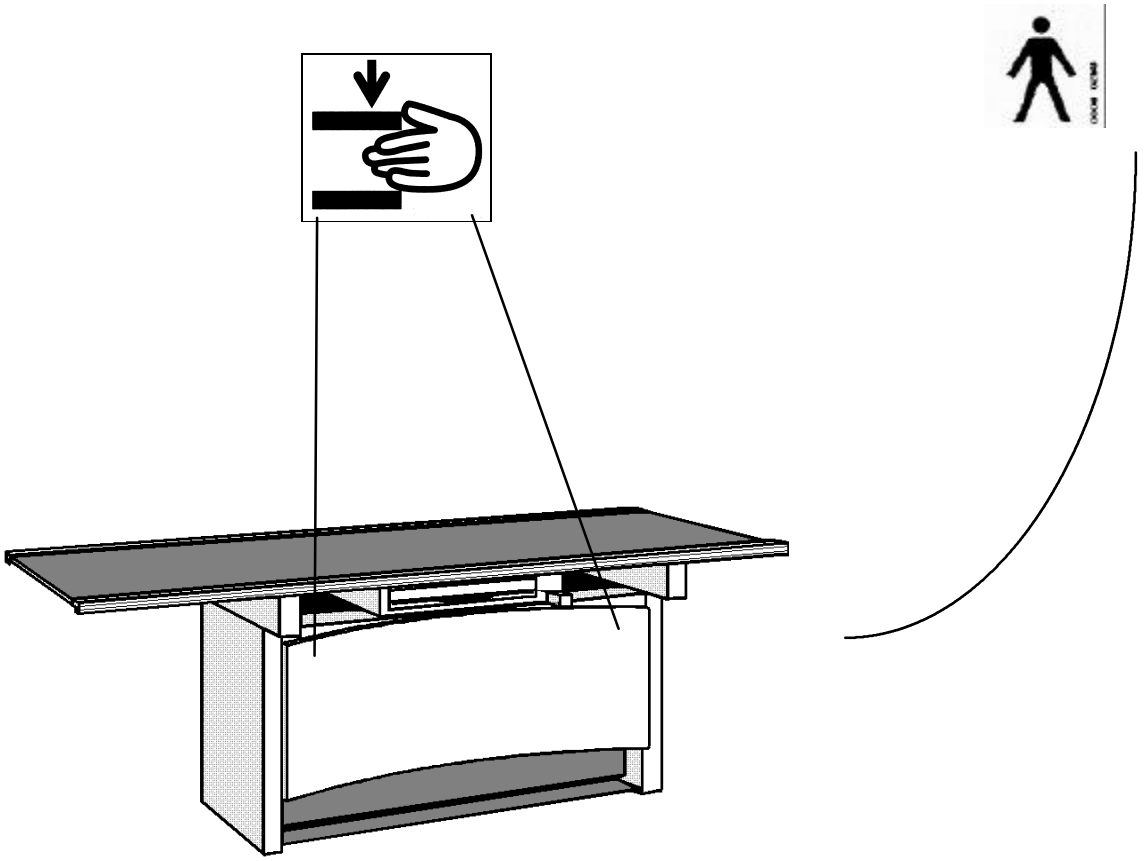
Name Plate Location:



Specifications are subject to change without notice. TV/Ru

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